

**Appl. No.** : **10/649,480**  
**Filed** : **August 27, 2003**

### **REMARKS**

Claims 2-11, 13-15, and 35 have been cancelled. Claim 1 has been amended. New claim 37 is added. Claims 1, 12, 16-34, and 36-37 are now pending in this application. Claims 16, 18, and 19 are withdrawn from consideration. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### **Election/Restrictions**

With this amendment, Applicants have amended claim 1 to be generic to the species identified as SEQ ID NOS: 1, 3, 4, AND 6. These species are now listed in new claim 37.

#### **Priority**

Claim 1 has been amended so that it is fully supported by the earliest priority application. The listing of specific SEQ ID NOS has been deleted from claim 1 and is now added as dependent claim 37. In addition, claim 1 has been amended to recite that injection of FGF-1 is into the ischemic region of the myocardium. Support for this amendment is found in parent application no. 09/358,780 at page 17, lines 28-29 and page 22, line 26. Support in provisional application no. 60/093,962 is found on page 18, lines 26-28 and page 23, line 26. General support for recombinant hFGF is found in the specification at pages 9, line 1 to page 17, line 7 (09/358,780) and at page 9, line 9 to page 18, line 5 of provisional application 60/093,962. It is respectfully submitted that claim 1 is completely supported by application No. 09/358,780, filed July 22, 1999 and the corresponding provisional application 60/093,962, filed July 24, 1998.

#### **Declaration**

The Office Action states that the Declaration of Dr. Stegmann filed on August 25, 2005 is insufficient to overcome the rejection over Schumacher, et al. because of the amendment to claim 1 filed with the paper of August 2005.

With the present paper, claim 1 has been amended so that claim 1 is fully supported by application No. 09/358,780, filed July 22, 1999 and the corresponding provisional application 60/093,962, filed July 24, 1998. The amendment filed August 2005 included a Declaration under in Re Katz to overcome the rejection over Schumacher, et al. and a Declaration under 37 C.F.R.

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§ 1.131 to overcome Htun, et al. Copies are resubmitted here for convenience. See response to grounds of rejection below.

Applicants respectfully request reconsideration of the previously submitted Declarations in view of Applicant's amendment of claim 1 so that it is now supported by the July 24, 1998 disclosure.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1-15, 17, 20-34, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schumacher, et al. (Circulation, Feb, 1998, Vol. 97, pp. 645-650) for claims 1, 3-11, 13-15, 20-22, 33, and 36, Jaye, et al. (U.S. Patent No. 5,571,790A) and Fasol. et al. (J. Thorac. Cardiovasc. Surg. 1994, Vol. 107, pp 1432-1439).

Applicant again presents the attached Declaration under In re Katz to overcome this ground of rejection in view of the present claim amendments. The present claim 1 is supported by Applicant's provisional application 60/093,962, filed July 24, 1998 as discussed above. Accordingly, Schumacher, et al. is no longer a reference under 35 U.S.C. § 102(b).

As presented with the August 2005 Amendment, Applicant is one of the co-authors of the cited reference. As set forth in the attached Declaration, the three co-authors worked under the direct guidance and direction of Applicant and did not contribute to the inventive concept of the claimed invention. Accordingly, the claimed invention was not described in a printed publication before the invention thereof by Applicant.

In view of the attached Katz Declaration, Applicant's amendment of claim 1, and the Remarks above, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1, 12 and 17 are rejected under 35 U.S.C. § 103(a) as being patentable over Pu, et al. (Circulation 1993, Vol. 88, No. 1, pages 208-215), Linemeyer (U.S. Patent No. 5,401,832) and Kordyum, et al. (U.S. Patent No. 6,773,899).

The ground of rejection is overcome by Applicant's amendment of claim 1. Claim 1 has been amended to recite that the recombinant hFGF is injected "into the ischemic region of the myocardium". The disclosure of Pu, et al. relates to revascularization of an ischemic limb.

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There is nothing in Pu, et al. that would teach or suggest to one of ordinary skill in the art that hFGF could be injected into an ischemic region of myocardium to induce local neoangiogenesis.

This deficiency is not corrected by either of Linemeyer or Kordyum, et al. Linemeyer, et al. merely disclose that FGF-1 may be used to promote revascularization of a grafted blood vessel. Linemeyer, et al. do not teach injection of FGF-1 into the myocardium.

Kordyum, et al. is not prior art to present claim 1, amended as discussed above, as the earliest possible date for the Kordyum, et al. reference is Aug. 15, 2000 based upon a provisional filing. The present claim 1 has priority from July 24, 1998. Furthermore, Kordyum, et al. also do not teach injection into the myocardium.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1, 12, 17 and 36 are rejected as being unpatentable over Banai, et al. (Cir. Res. 1991, Vol. 69, No. 1, pp 76-85), Linemeyer (U.S. Patent No. 5,401,832) and Kordyum, et al. (U.S. Patent No. 6,773,899).

Banai, et al. do not teach the invention claimed as Banai, et al. do not teach injection of FGF into the ischemic region of the myocardium. Rather Banai, et al. teach introduction of FGF using an epicardial sponge (see Abstract). One of ordinary skill in the art would not be motivated to directly inject FGF into a myocardium in view of Banai, et al. as Banai, et al. neither teaches nor suggests direct injection.

This deficiency is not corrected by either of Linemeyer or Kordyum, et al. for the reasons discussed above. As discussed above, Linemeyer, et al. do not teach injection of FGF-1 into the myocardium. Kordyum, et al. do not teach injection into the myocardium and is not prior art to the present claims.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1, 12, 17, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Htun, et al. (J. Mol. Cell. Cardiol April 1998, Vol. 30, pp 867-877), Linemeyer, et al. (U.S. Patent No. 5,401,832A), and Kordyum et al. (U.S. Patent No. 6,773,899B2).

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In order to overcome this ground of rejection, Applicant respectfully resubmits the Declaration under 37 C.F.R. § 1.131 previously submitted with the Amendment of August 2005. This Declaration was originally submitted in parent Application No. 09/358,780. The Declaration established that Applicant had completed his invention before January 9, 1997 which is before the date of the Htun, et al. reference, i.e. April 1998. In view of Applicant's amendments, claim 1 is now fully supported by Applicant's provisional application filed July 24, 1998. Accordingly, Applicant respectfully requests reconsideration of the Declaration under 37 C.F.R. § 1.131 in view of the amendments to claim 1.

In view of Applicant's amendments and the submitted Declaration under 37 C.F.R. § 1.131, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

Claims 1, 12, 17, 23-27, 34, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fasol, et al. (J. Thorac Cardiovasc. Surg. 1994, Vol. 107, pp.1432-1439), Linemeyer (U.S. Patent No. 5,401,832) and Kordyum, et al. (U.S. Patent No. 6,773,899).

Fasol, et al. differ from the presently claimed invention in that Fasol, et al. teaches a fibrin glue implant, not injection into the myocardium. Fasol, et al. teach implantation between the aorta and the myocardium of the left ventricle (see last two lines of page 1), not injection directly into the myocardium. As Fasol, et al. neither teach nor suggest injection into the myocardium, one of ordinary skill in the art would not be motivated to inject FGF into the myocardium in view of Fasol, et al.

This deficiency is not corrected by either of Linemeyer or Kordyum, et al. for the reasons as discussed above. As discussed above, Linemeyer, et al. do not teach injection of FGF-1 into the myocardium. Kordyum, et al. do not teach injection into the myocardium and is not prior art to the present claims.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**CONCLUSION**

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In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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